

Date 5/23/2016

Name of Evaluator - [REDACTED]

BIRD Project Evaluation Form

1. General Information

U.S. Company:

Becton, Dickinson and Co, Franklin Lakes, NJ

Israeli Company:

MedAware Ltd, Raanana, Israel

Project Title:

Prescription Error Surveillance

2. Budget

Project duration (months)	Israeli Company (\$)	Israeli Company (%)	U.S. Company (\$)	U.S. Company (%)	Total Budget (\$)
17	1,021,080	45	1,214,765	55	2,235,845

3. Evaluation

Area	Rating*	Explanation (expand below as needed)
Technology	A	Innovative Idea
Business Potential	B	Could expand to every EHR system
Capability of Companies	A	Sound resources
Overall Rating (average)	B	Patient Safety is biggest reward

* Rating: **A** = excellent, top proposal seen lately, **B** = good, high potential for success; **C** = fair, success with little innovation; **D** = problematic, lack details describing idea; **E**= recommend to reject, lacks details in multiple areas

4. Comments – (maximum three pages)

The Product and the Technology

(Include description of the technological innovation, challenges and assessment of technological risks)

Medication errors are an extremely deadly problem, and one of the largest safety issues facing electronic prescribing today. In the US, the “Meaningful Use” of Electronic Health Record Systems (EHRs) has been a goal of the National Coordinator (ONC) to improve both use of electronic systems and provide increased safety to the patient. A simple error in a prescription can have deadly results, for example, prescribing a Sulfa drug like penicillin when a patient is allergic to Sulfa drugs, or prescribing a medication for a patient when another doctor has already prescribed a medication that it is incompatible with. To eliminate these errors, the Meaningful Use program requires an EHR system to contain rules or “triggers” to alert a Doctor when irregularities in prescriptions occur. As the proposal notes, these systems are simple rule-base ones that only address the most rudimentary of the errors. The system proposed will go further down the available data and be able to catch many

more errors and more sophisticated ones and prevent accidental death due to allergic reaction or medical issue with a prescribed drug by analyzing much more data than is currently available.

Project Plan (Including major tasks, collaboration and share of responsibilities between partners, main milestones)

The project plan is very reasonable, MedAware has been in this business for a while and has the healthcare expertise needed to implement this. BD has the reasoning software needed to implement the solution, a good combination of talents. They need to move to a cloud implementation first to allow for the data flow and platform to do the analysis. The steps:

- 1) Setup infrastructure in BD private cloud to support MedAware application**
- 2) Prepare MedAware architecture to utilize BD MedMined cloud infrastructure**
- 3) Ensure HIPAA compliance of the existing MedAware application in a cloud environment**
- 4) Integrate MedAware with BD's MedMined platform**
- 5) Integration with BD's Care Coordination Engine**
- 6) Map MedMined data feeds with MedAware input requirements to ensure product functionality**
- 7) Create unified MedAware/MedMined user interface for customer alerts**
- 8) Create EMR interface to combined BD/MedAware solution with third party EMR providers**
- 9) Fund and expand the clinical trial**
- 10) Prepare the combined BD/MedAware solution for pilot testing on the BD infrastructure in a live environment**

The project plan is reasonable, the steps are sequenced correctly and no step requires more effort than they have allocated. I see no reason they cannot accomplish all targets.

The Budget (Realistic or not)

The budget of \$2,235,845.00 is split 55%/45% between the two companies, with BD getting the larger share. DB will be doing the development so it makes sense for them to have the larger share. Most of the effort is software development, so no hardware is needed, aside from the VMs they will run this on. SO this is a realistic budget, because it is mostly an integration problem, and should pose no surprises in cost. All effort is known upfront, with no dependencies on a research portion panning out.

The Market (Including evaluation of commercial potential)

Calendar year:	2018	2019	2020
Target market size for developed product (M\$):	250	250	250
Estimated market share (%):	0.3%	0.9%	1.7%
Estimated sales quantity (units):	10	30	60
Estimated representative unit price (\$/unit):	75,000	73,500	72,000
Estimated sales revenue (K\$):	750	2,205	4,320
Estimated cumulative sales revenue (K\$):	750	2,955	7,275

If this is a success, imagine every Hospital and every doctor's office having an electronic health record system that includes this software. The cost/benefit of saving lives because of this software is immeasurable. They can make a large impact in Patient Safety,

Capabilities of the Companies (Technical & commercial)

MedAware's team will lead the R&D activity of porting software from the deployed installations to BD-hosted models, and integrating its algorithms with BD MedMined's data streams. BD will provide the technological infrastructure and allocate FTEs to enable successful integration into the MedMined ecosystem. Both companies responsibilities are their exact strengths.

- BD's Technology Solutions team is comprised of more than 400 professionals, including solution architects, developers and project managers that over the years have executed multiple

complex IT development projects to launch new solutions into the market place, including MedMined's modules, Care Coordination Engine (connectivity middleware)

- BD's technology infrastructure includes secure, HIPAA compliant private and hybrid cloud environments to enable rapid solution deployment, as well as thousands of EMR and lab systems integrations with all major vendors installed at the customers' sites
- BD aggregates and normalizes millions of patient data points from various data feeds to enable care delivery optimization in the inpatient setting
- MedAware team is made up of members from companies specializing in network infrastructure, military elite computer units, as well as computer security companies
- MedAware already is fully integrated with three different EMR vendors and systems, including a live implementation in Sheba hospital. MedAware's system is based on an application server with capabilities of supporting distributed and heterogeneous environments

Production plans (Who, what, where, when, etc.)

Production of the proposed solution will be a joint effort between MedAware and BD. MedAware will be responsible for leading the R&D effort for porting the existing software from the current deployed model to the BD hosted solutions model. Moving to the BD hosted model will allow for single integration of the MedAware algorithms and machine learning process with the various BD MedMined clinical data streams and will enhance the ability to continuously learn and adapt as additional data is analyzed. BD will be responsible for deploying the proposed solution to future hosted solutions customers as well as support the hosted solution infrastructure, maintenance and customer support. Research and development teams for MedAware are located in Raanana, Israel. Research and development teams and hosted solutions information technology teams for BD are located in San Diego, CA, Reston, VA, Birmingham, AL, and Chandigarh, India. Product development will be maintained both organizations.

Benefit to the Israeli Company (If known)

Will expand their EHR product to a new market. This could increase their revenues many fold.

Benefit to the U.S. Company (If known)

Will allow them to branch their rules analysis based work to a new domain, the Medial analysis field. This could lead to other domains as well if this is a success.

Synergy between the Companies (If known)

There appears to be great synergy between these two companies, MedAware knows the Electronic Health Record portion of this project, they have been doing it for many years, BD has done the rules based analysis on other domains, so switching their efforts to a new domain should be minimal. I see that together they will be able to accomplish the tasks.

Pros (In your opinion)

1. Useful addition to every day medical practice because of the possibility to analyze great amount of data that cannot be taken into consideration by humans and establishing therapeutic norm.
2. Reporting every deviation and variation from established therapeutic norm helps lowering medical mistakes. Additionally, it should help discovering and improving therapeutic protocols through feedback given by medical professionals.
3. Bringing more objectivity to data analyzing process in clinical research. (too subjective right now)

The patient safety aspect is the greatest achievement they will have, you cannot put a price on the loss of human life, and this will prevent many prescribing errors.

Concerns (In your opinion)

1. To what extent the accuracy of conclusions inferred by MedAware's algorithms is influenced by mistakes in medical data that are analyzed?

2. Why is dosing support somewhat addressed (Table 8) if MedAware's algorithms analyze all medical data from system?
3. Who will review accuracy of the therapeutic protocol feedback given by different medical professionals?
4. Must make sure they understand the US Meaningful Use program and make sure their algorithms work with those requirements.
5. **MUST** make sure HIPPA requirements are followed, data has to be secure.